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Between June 1967 and December 1982, 872 attempts at intraaortic balloon pumping (IABP) were made in 733 patients. Nearly 75% of the patients were men; the proportion of women has increased in recent years. The principal indication for IABP support initially was cardiogenic shock, but over the years, preoperative support, weaning from cardiopulmonary bypass and unstable angina have become the primary indications. Complications of IABP were classified and distributed by severity (minor: I [15%] and II [26%]; major: III [3%] and IV [1%]) and type ([vascular [22%], infectious [22%], and bleeding [7%]). Vascular complication rates were higher in women (32 vs 18%, p = 0.0001), in diabetic patients (32 vs 20%, p = 0.003), and in hypertensive patients (27 vs 20%, p = 0.02). These did not vary with the duration of IABP support (range of duration 0 to 76 days). The rate of infectious complications was related to location where IABP was performed (coronary care unit 26%, operating room 12%). The rate of fever and bacteremia increased significantly with duration of IABP support, but the rate of local wound infection did not. In conclusion, most IABP complications are minor, resolve after balloon removal, are related to vascular status of the patient and, with the exception of bacteremia, are independent of IABP duration. (Am J Cardiol 1986;57:976–983)

Intraaortic balloon pumping (IABP) was first performed successfully in the clinical setting by Kantrowitz et al in 1967. The first patient in whom it was performed was in cardiogenic shock and had failed to respond to maximal application of pharmacologic therapy.[1] Because IABP was an effective means of support for this kind of patient,[2,3] other investigators began to explore its potential. As a result, it has become an accepted approach to circulatory assistance for patients presenting with a wide variety of indications.[4–6] As experience with IABP has accumulated, complications of the procedure have been identified. Several series of more than 100 patients have been reported[7–16] that have added to knowledge of IABP sequelae. However, little effort has been directed toward determining the incidence and outcome of complications according to clinically relevant patient subsets. We, therefore, analyzed our total clinical experience with IABP with the aim of identifying predictors of IABP complications.

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Methods

Clinical material: During the period under review—1967 through 1982—IABP evolved from an investigative method to a routine modality in cardiac intensive care. The data were analyzed, therefore, for 3 periods:

1967 through 1973—the years spanning the first clinical use of IABP in patients and its early use by a limited number of investigators (114 patients, era I).

1974 through 1979—the period in which IABP was adopted by many cardiac centers. The apparatus and adjunctive management remained substantially the same as in the earlier years (387 patients, era II).

1980 through 1982—the advent of a modified balloon pump, which allowed percutaneous insertion (232 patients, era III).

Thus, the series to be analyzed comprises 872 attempts at IABP in 733 patients. Thirty-seven of the patients were treated at Maimonides Medical Center in Brooklyn and the remaining 696 at Sinai Hospital of Detroit. For each insertion attempt, a physician examined the chart to determine identifying information; patient age and sex; relevant history; date of initiating and terminating IABP; IABP complications; nature of any contemporaneous cardiac surgery; findings at angiocardiography; indication for IABP; location in the hospital where insertion of the balloon pump was attempted; type of balloon pump used; causes of insertion failure; and therapy given before, during and after IABP. Duration of IABP and patient status at hospital discharge were also recorded; autopsy findings were noted when available. One hundred ninety variables for each IABP insertion attempt were coded and entered into a computer for analysis. The median duration of pumping was 72 hours (range of 0 to 76 days).

Since IABP was attempted in some patients more than once (either during the same hospital stay or during a subsequent admission), separate records were maintained for each procedure.

This report covers a span of 15 years. During this time, management of patients with cardiac disease (pharmacologic and surgical) has changed substantially. Most of the changes have also been introduced in the management of patients who undergo IABP. However, aspects of management specific to IABP have remained essentially unchanged[17-19] (except for the introduction of the percutaneous insertion technique). All patients (except during the early postoperative period) received heparin, as a bolus in era I and as an intravenous drip to maintain twice normal prothrombin time later. Most patients received prophylactic antibiotics.

Balloon pumping methods: Surgically placed balloon pumps were used in 776 insertion attempts. They were made initially in our laboratory and later by Plastron, Inc., the Milton Roy Company or Datascope. All were of the single-chamber design, 16 to 18 mm in diameter at the balloon, 4 mm at the catheter, and driven by helium. In 96 insertion attempts, the balloon pumps were of the Datascope Percor or Percor DL type.

Data analysis: In computing the incidence of complications, each insertion or insertion attempt was considered separately. In several categories (e.g., fever, bleeding, organ emboli) the relation to IABP could not always be defined. Accordingly, unless the complication was clearly unrelated to IABP, it was attributed to IABP.

Differences between categorical variables were tested for statistical significance using the chi-square analysis; continuous variables were compared to ascertain the significance of differences by means of the 2-tailed Student *t* test. A p value ≤ 0.05 was considered significant.

A multivariate risk factor analysis with a logistic regression model[20] was used to determine whether any combinations of predictor variables could define patient subsets at heightened risk of complications.

TABLE I Preexisting Conditions According to Sex

Condition	Female (n = 186) n	(%)	Male (n = 547) n	(%)	p Value	Total (n = 733) n	(%)
Diabetes mellitus	53	(29)	79	(14)	0.00001	132	(18)
Systemic hypertension	90	(48)	166	(40)	0.00001	256	(35)
Valvular heart disease	22	(12)	33	(6)	0.009	55	(8)
Coronary artery disease	112	(60)	354	(65)	0.2	466	(64)
Myocardial infarction	68	(37)	256	(47)	0.01	324	(44)
Cerebrovascular accident	19	(10)	26	(5)	0.007	45	(6)
Peripheral vascular disease	12	(7)	25	(5)	0.3	37	(5)
Congestive heart failure	48	(26)	105	(19)	0.05	153	(21)

Results

Characteristics of the patient population and preexisting conditions: Five hundred forty-seven of the patients (75%) were men and 186 (25%) were women. In era I, the ratio of male to female patients was more than 3:1, but dropped to 2:1 later. The median age of the patients was 58 years (57 for men and 62 for women) (range 16 to 87) (Fig. 1).

Conditions diagnosed before each patient's referral for IABP are summarized by sex in Table I. Many patients had more than 1 antecedent condition. The incidence of diabetes mellitus, systemic hypertension, valvular heart disease, cerebrovascular accident and congestive heart failure was higher in women than men. Men had significantly more myocardial infarctions. Table II shows preexisting conditions according to the era when IABP was carried out. The frequency of preexisting systemic hypertension and coronary artery disease increased significantly over the eras, while that of congestive heart failure decreased, reflecting the trend of treating patients with acute ischemia without left ventricular power failure.

Indications for intraaortic balloon pumping: Table III is a list of indications for IABP during the 3 eras. In era I, the principal indication was myocardial infarction with cardiogenic shock (57%); in era II it was preoperative support (23%); and in era III it was unsta-

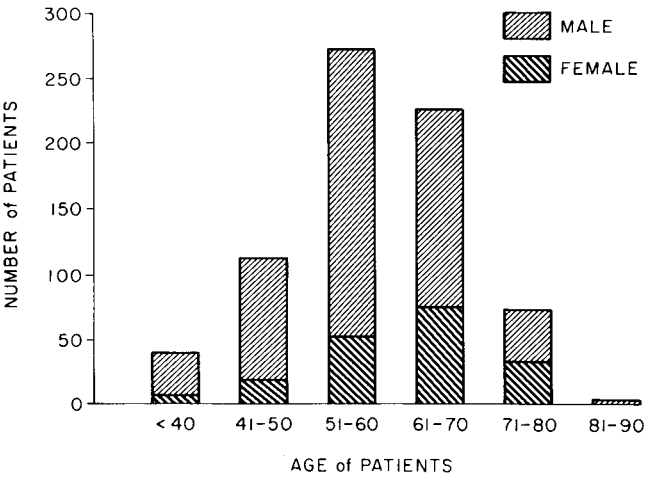

FIGURE 1. Age and sex distribution of the 733 patients in this study.

TABLE II Preexisting Conditions According to Era

Condition	Era I (n = 114) n	(%)	Era II (n = 387) n	(%)	Era III (n = 232) n	(%)	p Value
Diabetes mellitus	25	(22)	64	(17)	43	(19)	0.4
Systemic hypertension	23	(20)	131	(34)	102	(44)	0.0001
Valvular heart disease	9	(8)	35	(9)	11	(5)	0.1
Coronary artery disease	54	(47)	241	(62)	171	(74)	0.0001
Myocardial infarction	42	(37)	173	(45)	109	(47)	0.1
Cerebrovascular accident	5	(4)	20	(5)	20	(9)	0.1
Peripheral vascular disease	4	(4)	15	(4)	18	(8)	0.07
Congestive heart failure	36	(32)	73	(19)	44	(19)	0.009

ble angina with or without myocardial infarction (33%). Many patients presented with more than 1 indication. More women than men needed IABP during discontinuation of cardiopulmonary bypass and for management of postoperative myocardial failure.

Insertion failure: In 652 patients (89%), the first attempt to insert the balloon pump was successful and in 46 (6%) 2 or more attempts were required. The balloon pump could not be placed in 35 patients (5%). Thus, 95% of the attempts to insert the balloon pump were successful.

IABP insertion failed more frequently in patients who had a history of peripheral vascular disease (41%) than in others (10%, p = 0.0001). For patients who had had systemic hypertension for 10 years or more, the failure rate was 29%, whereas for those who had a shorter history of systemic hypertension it was 11% (p = 0.001), which was the same as for patients with no history of hypertension. The frequency of insertion failure did not vary significantly according to balloon pump type (surgical 6%; percutaneous 7%; p = 0.8).

Complications: IABP complications were classified and distributed by severity (categories I through IV) and type (vascular, infectious and bleeding):

Category I—spontaneous resolution without treatment, with IABP in situ (e.g., serosanguinous discharge, loss of pulse, temperature spike) (frequency 15%).

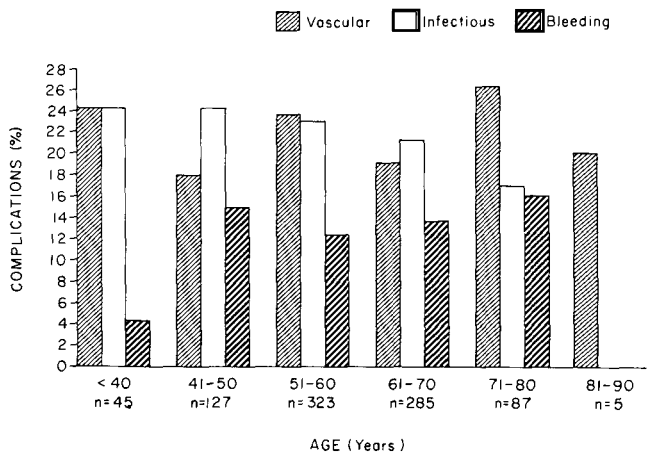

FIGURE 2. Distribution of vascular, infectious and bleeding complications according to patient age (in decades).

TABLE III Frequency of Indications for Intraaortic Balloon Pumping, by Era

Indications	Era I (n = 114) (%)	Era II (n = 387) (%)	Era III (n = 232) (%)	p Value
MR, no MI	0	1	0.4	0.7
Unstable angina, no MI	2	18	18	0.001
Arrhythmia, no MI	0	2	1	0.3
CHF, no MI, no cardiomyopathy	8	5	3	0.2
MI	0	2	1	0.3
MI with VSD	2	3	3	0.8
MI with cardiogenic shock	57	20	16	0.0001
MI with MR	2	2	4	0.1
MI with unstable angina	4	9	15	0.0001
MI with CHF	4	2	1	0.1
MI with other	0	1	3	0.1
Weaning from CPB	7	8	12	0.1
Cardiomyopathy	1	1	0	0.1
Preoperative support	7	23	15	0.0002
Postoperative support	4	6	6	0.4
Cardiogenic shock, no MI	3	1	1	0.2
Other	1	1	1	0.5

CHF = congestive heart failure; CPB = cardiopulmonary bypass; MI = myocardial infarction; MR = mitral regurgitation; VSD = ventricular septal defect.

Category II—resolution after treatment or removal of IABP (e.g., ischemia of limb, fever, bleeding from arteriotomy, infection) (frequency 26%).

Category III—residual deficit (e.g., amputation, foot drop or other ischemic neuropathies, embolization) (frequency 3%).

Category IV—contributory cause of death (e.g., retroperitoneal bleeding from ruptured iliac artery, bacteremia, cardiac arrest during femoral artery embolectomy under general anesthesia) (frequency 1%).

Complications in categories I and II are considered minor; those in categories III and IV are considered major.

Figure 2 shows the distribution of vascular and infectious complications by patient age. Table IV is a list of frequencies of complications by era.

Vascular complications: Twenty-two percent of IABP insertion attempts resulted in vascular complications. Figure 3 shows the relation of duration of pumping and vascular complication rate. The following specific complications are included under vascular complications:

Loss of distal pulse: Loss of lower-extremity pulse was recorded in 118 patients (14% of insertion attempts). The 38 patients with category I complications had transient episodes. The 68 patients with category II complications recovered after removal of the balloon pump, with or without thromboembolectomy. Four of the 12 patients with category III complications had to undergo amputation and 8 sustained neurologic impairment and are included in the list of neurologic complications.

Pain in the leg: Forty-two patients (5% of insertion attempts) reported pain in the leg in which the balloon pump was inserted. Seven such episodes were placed in category I and 26 in category II. Nine patients had vascular or neurologic complications and are included below.

Thromboembolism: In 86 patients (10% of insertion attempts), routine embolectomy after removal of the balloon pump harvested thrombi. This procedure alone restored the peripheral circulation in 81 patients (category II). One of the remaining 5 patients had residual neurologic impairment. Two patients who had a second embolectomy under general anesthesia died of cardiac arrest. Distal embolization occurred in 2 patients. In 1 patient the sigmoid colon had to be resected, and in the other, cerebral emboli caused paresis of the right hand.

Neurologic complications: Twenty-five patients (3% of insertion attempts) had neurologic impairment. Ten patients had transient paresthesia that required no treatment (category I) and 3 had ischemic neuropathy that was overcome after physiotherapy (category II). Eight patients, however, had residual neurologic impairment of the limb distal to the arteriotomy and 4 had foot drop.

Delayed vascular complications: Eight patients (1% of insertion attempts) experienced delayed vascular complications. Femoral bypass or angioplasty was performed in 5 patients to correct conditions identified after hospital discharge. In addition, there was delayed occurrence of ischemic foot ulcer (1 patient), foot drop (1 patient), and femoral neuropathy for which physical therapy was required (1 patient).

Amputation: Four patients required amputation, in 1 patient above the knee and in 2 at the midmetatarsal level; the big toe of 1 patient was removed because of gangrene.

Aortic dissection: Aortic dissection was discovered in 4 patients. These represented 0.5% of all patients, or 3% of the 131 patients in whom autopsy was performed.

Other vascular complications: Surgical revascularization or angioplasty of the femoral artery was necessary in 15 patients (2% of insertion attempts). Four patients had ischemic foot ulcer. Gangrene of the leg or foot was imminent in 2 patients at the time of death.

TABLE IV Frequencies of Complications by Era

Complications	Era I (n = 114) (%)	Era II (n = 387) (%)	Era III (n = 232) (%)	p Value
Vascular				
Loss of distal pulses	13	10	22	0.0001
Pain in the leg	7	4	6	0.4
Thrombosis, emboli	7	9	14	0.04
Neurological complications	7	1	4	0.004
Delayed vascular complications	3	1	0.4	0.1
Amputation	1	0.5	0.4	0.8
Aortic dissection	1	0.8	0	0.3
Infectious				
Local infection	4	5	8	0.1
Fever	20	21	25	0.5
Bacteremia	0	2	1	0.2
Bleeding	9	17	13	0.07

Table V is a comparison of selected subsets of patients with regard to the frequency of vascular complications. Women with a history of diabetes mellitus or systemic hypertension and those in whom IABP was initiated outside the operating room had vascular complications more frequently. As would be expected, the frequency of complications was also higher in those in whom the insertion attempt succeeded and in those who survived IABP.

Infectious complications: Twenty-two percent of IABP insertion attempts resulted in infectious complications. Figure 4 shows the relation of infectious complications to duration of pumping.

Fever: One hundred fifty-six patients (18% of insertion attempts) had fever; 71 were in category I and 85 were in category II.

Local infection: Forty-three patients had local infection at the insertion site (5% of all insertion attempts). These patients all recovered completely with treatment; in 1 case, therapy included drainage of a retroperitoneal abscess. The rate of local infection tended to increase in era III (8% of insertion attempts) compared with eras I (4%) and II (5%), but the differences were not statistically significant.

Bacteremia: Twelve cases of bacteremia (1.4% of all insertion attempts) were attributed to balloon pumping. After treatment, 9 patients recovered com-

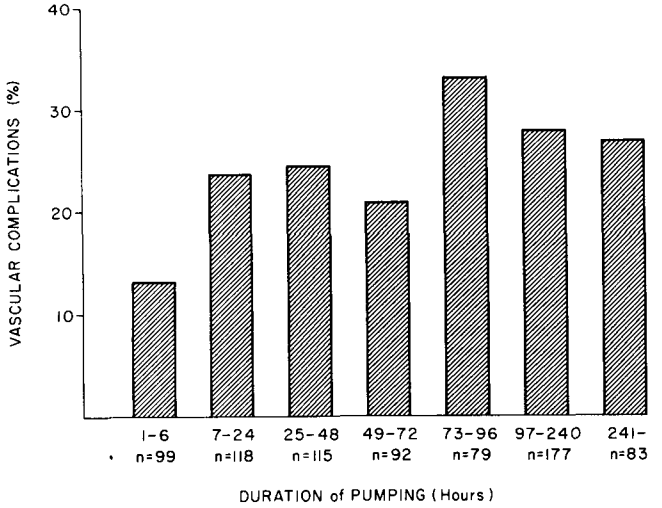

FIGURE 3. Relation between duration of intraaortic balloon pump support and rate of vascular complications.

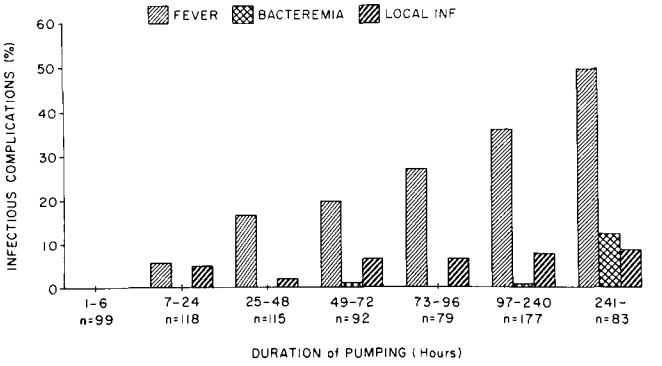

FIGURE 4. Distribution of fever, local infection and bacteremia according to duration of pumping.

TABLE V Vascular and Infectious Complications: Frequencies in Selected Subsets of Patients

	n	Vascular Complications (%)	p Value	Infectious Complications (%)	p Value
Sex					
Male	640	(18)		(22)	
			0.0001		0.8
Female	232	(32)		(22)	
Age (yr)					
>50	713	(22)		(28)	
			0.5		0.4
<50	159	(20)		(25)	
History of					
Diabetes mellitus	122	(32)		(23)	
			0.003		0.8*
No diabetes mellitus	750	(20)		(22)	
Systemic hypertension	239	(27)		(22)	
			0.02		0.9
No hypertension	633	(20)		(22)	
CAD	436	(23)		(26)	
			0.6		0.01
No CAD	436	(21)		(19)	
Indication for support					
Cardiogenic shock	228	(25)		(25)	
			0.1		0.1
No cardiogenic shock	644	(21)		(21)	
Successful insertion					
Yes	765	(24)		(25)	
			0.0001		0.0001
No	107	(5)		(5)	
Emergency insertion					
Yes	740	(22)		(23)	
			0.5		0.03
No	132	(20)		(15)	
Location of insertions					
CICU	517	(23)		(26)	
SICU	126	(21)		(23)	
OR	137	(14)	0.06	(12)	0.007
Cath lab	42	(33)		(17)	
Other	50	(24)		(14)	
Survivors					
Yes	487	(24)		(28)	
			0.04		0.0001
No	385	(19)		(15)	

* However, diabetics had a higher frequency of local infections, 9% vs 4% (p = 0.02).

CAD = coronary artery disease; Cath lab = catheterization laboratory; CICU = cardiac intensive care unit; OR = operating room; SICU = surgical intensive care unit.

pletely, including 1 patient in whom bacteremia had been complicated by acute renal failure. Three patients died of septicemia and multiple organ failure (category IV).

Table V is a comparison of the frequency of infectious complications in selected subsets of patients. Those with a history of coronary artery disease, those in whom IABP insertion was performed on an emergency basis, and those in whom it was attempted outside the operating room had a higher frequency of infectious complications. Not surprisingly, the incidence of such sequelae was higher in patients who survived and in those in whom IABP insertion was successful.

Bleeding: In 63 instances (category I, 7% of insertion attempts), bleeding at the insertion site was minimal and required no treatment. In 51 instances (category II, 6%), the volume exceeded 200 ml, and multiple dressing changes were made. Bleeding due to heparin administration resulted in hematuria in 1 patient and hematemesis in another. Two other patients had thrombocytopenia, probably secondary to heparin administration.

Table VI shows the distribution of complications by severity according to the indications for IABP support.

In 14 patients, a leak in the balloon pump, evidenced by dark brown powder in the tubing (dehydrated blood), was observed. All these balloon pumps were replaced without complications.

Definition of patient subsets by logistic regression analysis: Logistic regression models that attempted to find combinations of predictor variables (demographic, preexisting condition, indications and duration of IABP) that were explanatory of complications (categorized into severity of symptom subgroups) were of limited value. When a second or third predictor was entered into a model, only a very minor additional variation in the complication was accounted for in

TABLE VI Severity of Complications by Indication for Intraaortic Balloon Pump Support

Indications	n	Minor Complications I n (%)	Minor Complications II n (%)	Major Complications III n (%)	Major Complications IV n (%)
MR, no MI	3	—	1 (33)	—	—
Unstable angina, no MI	114	29 (25)	37 (34)	3 (3)	1 (1)
Arrhythmia, no MI	8	—	2 (25)	1 (13)	—
CHF, no MI, no cardiomyopathy	37	3 (8)	12 (32)	—	1 (3)
MI	10	1 (10)	5 (50)	—	—
MI with VSD	18	2 (11)	8 (44)	2 (11)	—
MI with cardiogenic shock	179	25 (14)	46 (26)	10 (6)	1 (1)
MI with MR	17	—	6 (35)	—	—
MI with unstable angina	63	10 (16)	27 (43)	2 (3)	1 (2)
MI with CHF	14	1 (7)	2 (14)	—	—
MI with other	11	3 (27)	—	1 (9)	1 (9)
Weaning from CPB	65	8 (12)	10 (15)	2 (3)	—
Cardiomyopathy	7	1 (14)	3 (43)	—	—
Preoperative support	131	22 (17)	29 (22)	3 (2)	—
Postoperative support	42	2 (5)	9 (21)	1 (2)	—
Cardiogenic shock, no MI	8	2 (25)	1 (13)	—	1 (13)
Other	6	1 (17)	1 (17)	—	—
Total	733	110 (15)	199 (27)	25 (3)	6 (0.8)

CHF = congestive heart failure; CPB = cardiopulmonary bypass; MI = myocardial infarction; MR = mitral regurgitation; VSD = ventricular septal defect.

comparison to the amount of variation accounted for by a predictor variable singly. Further, the sample sizes were usually too small when combinations of symptoms (for a given complication) and predictor variables were considered to make the logistic model stable.

Survival: Fifty-eight percent of the patients were discharged alive from the hospital. More men survived (61%) than women (50%). Over the 3 eras, the survival rate improved, more impressively in women than in men (Fig. 5).

Survival rates according to preexisting conditions and indications are shown in Tables VII and VIII.

Discussion

Since its first clinical trials in 1967, IABP has been widely adopted for a widening range of indications. In its initial applications, the procedure was performed in patients whose life-threatening conditions made the risk of significant complications acceptable, but as IABP has come to be attempted for a variety of elective indications, it has become increasingly important to determine the nature and the severity of the attendant risk. Several large series of patients have been reported.[4,7-10,12,14,16,21,22] Gottlieb et al[16] attempted to distribute the risk of complications by patient subsets using a multivariate analytical technique.

In our analysis, we sought to obtain a broad view of IABP sequelae. Therefore, we defined "complications" so as to include all episodes, even those that were resolved completely. In addition, we counted instances in which the causal role of IABP was uncertain. This policy explains why our overall complication rate of 45% of all insertion attempts appears to be relatively high compared with rates reported by those who defined "complications" differently.

TABLE VII Patient Survival According to Preexisting Conditions

Condition	Survivors n	Survivors (%)
Diabetes mellitus (n = 132)	75	(57)
Systemic hypertension (n = 256)	160	(62)
Valvular heart disease (n = 55)	21	(38)
Coronary artery disease (n = 466)	299	(64)
Myocardial infarction (n = 324)	194	(60)
Cerebrovascular accident (n = 45)	25	(56)
Peripheral vascular disease (n = 37)	17	(46)
Congestive heart failure (n = 153)	71	(46)

Because our series of patients who underwent IABP is relatively large, it offered an opportunity to attempt to define subgroups at special risk of IABP-related complications. However, although a variety of statistically significant relationships was found, we could not identify combinations of predictor variables that were appreciably more powerful than single predictor variables in accounting for the variation in distribution of complications. It is theoretically possible, but unlikely, that an analysis of a substantially larger sample of IABP patients might allow recognition of clinically meaningful subgroups at heightened risk of certain complications.

Most IABP complications in our series and in other series were vascular[11,14,18,23-25]; the outcome was usually complete recovery and only a few patients (0.5% in our study) required amputation[24,25] or demonstrated aortic dissection (0.5%).[12,14,26-28]

Women had a significantly higher rate of vascular complications than men (32% vs 18%). Gottlieb et al[16] proposed that this difference may be due to sex-linked differences in the caliber of arteries. We concur with this, but in addition, in our IABP population, more women than men had diabetes and systemic hypertension, both of which are predisposing factors to vascular complications in our series.

In patients in whom the balloon pump could not be inserted, the vascular complication rate was significantly lower than in patients in whom the procedure was performed. In addition, the duration of IABP support and the frequency of vascular complications did

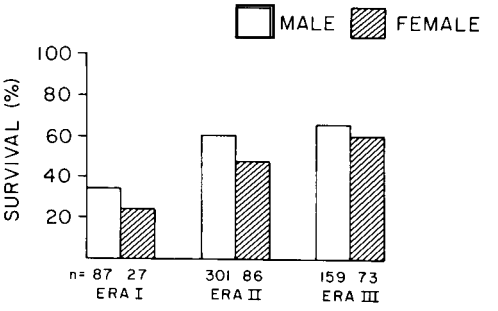

FIGURE 5. Distribution of survival in men and women by era.

TABLE VIII Patient Survival According to Indication for Intraaortic Balloon Pump Support

Indications	Survivors	
	n	(%)
MR, no MI (n = 3)	—	—
Unstable angina, no MI (n = 114)	99	(87)
Arrhythmia, no MI (n = 8)	5	(63)
CHF, no MI, no cardiomyopathy (n = 37)	21	(57)
MI (n = 10)	7	(70)
MI with VSD (n = 18)	3	(17)
MI with cardiogenic shock (n = 179)	58	(32)
MI with MR (n = 17)	10	(59)
MI with unstable angina (n = 63)	54	(86)
MI with CHF (n = 14)	3	(21)
MI with other (n = 11)	3	(27)
Weaning from CPB (n = 65)	25	(39)
Cardiomyopathy (n = 7)	3	(43)
Preoperative support (n = 131)	109	(83)
Postoperative support (n = 42)	20	(48)
Cardiogenic shock, no MI (n = 8)	1	(13)
Other (n = 6)	4	(67)

CHF = congestive heart failure; CPB = cardiopulmonary bypass; MI = myocardial infarction; MR = mitral regurgitation; VSD = ventricular septal defect.

not correlate (Fig. 3). These 2 findings imply that vascular complications are related to initial IABP placement rather than to the prolonged presence of the balloon pump in the vascular system. Isner et al,[29] on the basis of an examination of autopsy material, came to a similar conclusion.

The incidence of vascular complications also did not rise with age. The highest rate observed, 26% in patients 71 to 80 years old, was close to the 24% rate in those younger than 40 years (Fig. 2). In this respect, our findings are similar to those of Gottlieb et al[16] and Shahian et al.[22] The same was true for the infection rate.

The group at highest risk of vascular complications comprised diabetic patients (32% vs 20%). However, most such complications resolved completely, and the amputation rate was less than 1%. Diabetic patients who required insulin had an even higher vascular complication rate (53%).

Patients with a history of systemic hypertension also had vascular complications more frequently (27%) than others (20%). This finding and the observation that prior coronary artery disease was associated with a higher frequency of infectious complications (26% vs 19%) support the view that IABP complications are related to associated diseases and to IABP.[21] Patients who underwent IABP for cardiogenic shock had almost the same rate of vascular complications as those who underwent IABP for other indications. Patients who underwent IABP on an emergency basis compared with those who underwent it electively. These findings suggest that the patient's hemodynamic status per se is not an important variable in accounting for the distribution of vascular complications.

The frequency of neurologic complications, thrombosis and loss of peripheral pulse all increased in recent years (Table IV). This may reflect augmented survival, a higher index of diagnostic suspicion, and more accurate recording of the patient's condition.

The hospital location in which IABP was initiated affected the frequency of both vascular and infectious complications, but the former was not statistically significant. The highest frequencies of infectious complications were observed in the coronary care unit (26%) and the surgical intensive care unit (23%) and the lowest rates were in the operating room (12%) and catheterization laboratory (17%). These findings can be attributed partly to the varying degree of sterility in the 4 locations and the emergency status of the patient, which necessitates immediate action under conditions that may be less than optimal.

Contrary to the findings of a previous report,[11] the rate of local wound infection did not increase with duration of pumping; however the frequency of fever and bacteremia did (Fig. 4). Patients undergoing IABP support usually have 2 or more intravascular monitoring lines as well as the balloon pump. The presence of these lines is an additional factor in the incidence of fever and bacteremia.[30] As expected, both vascular and infectious complications were significantly more common in patients who survived.

The morbidity associated with IABP support is low (Table VI); complications that cause residual deficit occur in only 3% of IABP patients and in less than 1% it is a contributory cause of death.

The question of whether the use of a percutaneous balloon pump would alter any of these observations is timely. In this retrospective study, we could not determine this because the selection of the type of balloon pump used was based in part on the condition of the patient. To eliminate this bias, a separate prospective study was carried out.[15] One hundred one patients were randomly assigned either percutaneous (50 patients) or surgical (51 patients) IABP insertion. In the group with percutaneous insertion, 1 patient had severe leg ischemia requiring immediate termination of IABP assistance and 10 patients required Fogarty thrombectomy after elective IABP removal. In the surgical group, 2 patients had leg ischemia that required surgical intervention, 3 had septicemia and 1 patient had cerebral embolus. We conclude that although the percutaneous technique for IABP insertion is faster than the surgical technique and is technically simple, it is associated with a higher incidence of vascular complications.

The survival rate in men was higher than that in women. That women in our series were older and had a higher rate of diabetes mellitus, systemic hypertension, congestive heart failure and valvular heart disease may explain this finding. The improved survival in both sexes in recent years (Fig. 5) corresponds to changes in patient population (Table III). A larger proportion of patients underwent IABP for unstable angina, with or without myocardial infarction, and preoperative support, both of which have relatively high survival rates (Table VIII).

The data from patients who have undergone IABP for more than 20 days were analyzed in greater detail and are the subject of a report in preparation. Of 27

such patients, 17 (63%) were discharged from the hospital. Eight were long-term survivors (average 5 years, range 2.5 to 9).

References

1. Kantrowitz A, Tjønneland S, Freed PS, Phillips SJ, Butner AN, Sherman JL Jr. *Initial clinical experience with intraaortic balloon pumping in cardiogenic shock. JAMA 1968;203:113–118.*
2. Kantrowitz A, Krakauer JS, Rosenbaum A, Butner AN, Freed PS, Jaron D. *Phase-shift balloon pumping in medically refractory cardiogenic shock. Arch Surg 1969;99:739–743.*
3. Scheidt S, Wilner G, Mueller H, Summers D, Lesch M, Wolff G, Krakauer J, Rubenfire M, Fleming P, Noon G, Oldham N, Killip T, Kantrowitz A. *Intra-aortic balloon counterpulsation in cardiogenic shock. N Engl J Med 1973; 288:979–984.*
4. Foster ED, Olsson CA, Rutenburg AM, Berger RL. *Mechanical circulatory assistance with intra-aortic balloon counterpulsation for major abdominal surgery. Ann Surg 1976;183:73–76.*
5. Bonchek LI, Olinger GN. *Intra-aortic balloon counterpulsation for cardiac support during noncardiac operations. J Thorac Cardiovasc Surg 1979;78:147–149.*
6. Baudet M, Rigaud M, Rocha P, Bardet J, Bourdarias JP. *Treatment of early postinfarction ventricular aneurysm by intra-aortic balloon pumping and surgery. J Thorac Cardiovasc Surg 1979;78:445–451.*
7. Lefemine AA, Kosowsky B, Madoff I, Black H, Lewis M. *Results and complications of intraaortic balloon pumping in surgical and medical patients. Am J Cardiol 1977;40:416–420.*
8. Beckman CB, Geha AS, Hammond GL, Baue AE. *Results and complications* of intraaortic balloon counterpulsation. Ann Thorac Surg 1977;24:550–559.
9. Pace PD, Tilney NL, Lesch M, Couch NP. *Peripheral arterial complications of intraaortic balloon counterpulsation. Surgery 1977;82:685–688.*
10. McEnany MT, Kay HR, Buckley MJ, Daggett WM, Erdmann AJ, Mundth ED, Rao RS, deToeuf J, Austen WG. *Clinical experience with intraaortic balloon pump support in 728 patients. Circulation 1978;58:suppl I:I-124–I-132.*
11. Macoviak J, Stephenson LW, Edmunds LH Jr, Harken A, MacVaugh H III. *The intraaortic balloon pump: an analysis of five years' experience. Ann Thorac Surg 1980;29:451–458.*
12. Sturm JT, McGee MG, Fuhrman TM, Davis GL, Turner SA, Edelman SK, Norman JC. *Treatment of postoperative low output syndrome with intraaortic balloon pumping: experience with 419 patients. Am J Cardiol 1980;45:1033–1036.*
13. Alpert J, Parsonnet V, Goldenkranz RJ, Bhaktan EK, Brief DK, Brenner BJ, Gielchinsky I, Abel RM. *Limb ischemia during intra-aortic balloon pumping: indication for femorofemoral crossover graft. J Thorac Cardiovasc Surg 1980;79:729–734.*
14. Goldman BS, Hill TJ, Rosenthal GA, Scully HE, Weisel RD, Baird RJ. *Complications associated with use of the intra-aortic balloon pump. Can J Surg 1982;25:153–156.*
15. Goldberg M, Kantrowitz A, Rubenfire M, Goodman G, Freed PS, Hallen L, Reiman P. *Intraaortic balloon pump insertion: a randomized study comparing percutaneous and surgical techniques (abstr). JACC 1984;3:505.*
16. Gottlieb SO, Brinker JA, Borkon AM, Kallman CH, Potter A, Gott VL, Baughman KL. *Identification of patients at high risk for complications of intraaortic balloon counterpulsation: a multivariate risk factor analysis. Am J Cardiol 1984;53:1135–1139.*
17. Krakauer JS, Rosenbaum A, Freed PS, Jaron D, Kantrowitz A. *Clinical management ancillary to phase-shift balloon pumping in cardigenic shock. Amer J Cardiol 1971;27:129–138.*
18. Kantrowitz A. *Aortic balloon pumping in the management of left ventricular failure and cardiogenic shock. In: Meltzer LE, Dunning DL, eds. Textbook of Coronary Care. Amsterdam: Excerpta Medica, 1972:594–607.*
19. Kantrowitz A. *Mechanical assistance to the circulation in shock. In: Hardaway III RM, ed. Shock: Irreversible Stage of Dying. John Wright PSG Inc., 1987, in press.*
20. Neter J, Wasserman W. Applied Linear Statistical Model. *Homewood, IL: R.D.Irwin, 1974:9.*
21. Downing TP, Miller DC, Stinson EB, Burton NA, Oyer PE, Reitz BA, Jamieson SW, Shumway NE. *Therapeutic efficacy of intraaortic balloon pump counterpulsation. Circulation 1981;64:suppl II:II-108–II-113.*
22. Shahian DM, Neptune WB, Ellis Jr FH, Maggs PR. *Intraaortic balloon pump morbidity: a comparative analysis of risk factors between percutaneous and surgical techniques. Ann Thorac Surg 1983;36:644–653.*
23. Michels R, Haalebos M, Kint PP, Hagemeijer F, Balkumaran K, van der Brand M, Serruys PW, Hugenholtz PG. *Intra aortic balloon pumping in myocardial infarction and unstable angina. Eur Heart J 1980;1:31–43.*
24. Hauser AM, Gordon S, Gangadharan V, Ramos RG, Westveer DC, Garg AK, Timmis GC. *Percutaneous intraaortic balloon counterpulsation, clinical effectiveness and hazards. Chest 1982;82:422–425.*
25. O'Rourke MF, Sammel N, Chang VP. *Arterial counterpulsation in severe refractory heart failure complicating acute myocardial infarction. Br Heart J 1979;41:308–316.*
26. Weintraub RM, Aroesty JM, Pauline S, Levine FH, Markis JE, LaRaia PJ, Cohen SI, Kurland GF. *Medically refractory unstable angina pectoris. I. Long-term follow-up of patients undergoing intraaortic balloon counterpulsation and operation. Am J Cardiol 1979;43:877–882.*
27. Tobias MA, Challen PD, Franklin CB, Phillips G, Varley EM. *Intra-aortic balloon counterpulsation. Anaesthesia 1979;34:844–854.*
28. Harvey JC, Goldstein JE, McCabe JC, Hoover EL, Gay Jr. WA, Subramanian VA. *Complications of percutaneous intraaortic balloon pumping. Circulation 1981;64:suppl II:II-114–II-117.*
29. Isner JM, Cohen SR, Virmani R, Lawrinson W, Roberts WC. *Complications of the intraaortic balloon counterpulsation device: clinical and morphologic observations in 45 necropsy patients. Am J Cardiol 1980;45:260–268.*
30. Band JD, Maki DG. *Infections caused by arterial catheters used for hemodynamic monitoring. Am J Med 1979;67:735–741.*